



BILLING CODE 3410-34-P

**DEPARTMENT OF AGRICULTURE**

**Animal and Plant Health Inspection Service**

**[Docket No. APHIS-2020-0023]**

**BASF Corporation; Determination of Nonregulated Status of Plant-Parasitic, Nematode-Protected and Herbicide-Tolerant Soybean**

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Notice.

**SUMMARY:** We are advising the public of our determination that soybean designated as event GMB151, which has been developed using genetic engineering for resistance to the plant-parasitic nematode, soybean cyst nematode (*Heterodera glycines*), and for tolerance to 4-hydroxyphenylpyruvate dioxygenase (HPPD-4) inhibitor herbicides, is no longer considered regulated. Our determination is based on our evaluation of data submitted by BASF Corporation in its petition for a determination of nonregulated status, our analysis of available scientific data, and public comments received in response to our previous notices announcing the availability of the petition for nonregulated status and its associated draft environmental assessment and draft plant pest risk assessment. This notice also announces the availability of our final environmental assessment, final plant pest risk assessment, written determination, and finding of no significant impact.

**DATES:** This change in regulatory status was recognized on March 9, 2022.

**ADDRESSES:** You may read the documents referenced in this notice and the comments we received at [www.regulations.gov](https://www.regulations.gov) and entering APHIS-2020-0023 in the Search field. You can also view them in our reading room, which is located in room 1620 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room

hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

Supporting documents are also available on the APHIS website at <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status> under APHIS Petition 19-317-01p.

**FOR FURTHER INFORMATION CONTACT:** Ms. Cindy Eck, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1238; (301) 851-3892, email: [cynthia.a.eck@usda.gov](mailto:cynthia.a.eck@usda.gov). To obtain copies of the supporting documents for this petition, contact Ms. Cindy Eck at (301) 851-3892, email: [cynthia.a.eck@usda.gov](mailto:cynthia.a.eck@usda.gov).

**SUPPLEMENTARY INFORMATION:**

Under the authority of the plant pest provisions of the Plant Protection Act (PPA) (7 U.S.C. 7701 *et seq.*), the regulations in 7 CFR part 340, "Movement of Organisms Modified or Produced Through Genetic Engineering," regulate, among other things, the importation, interstate movement, or release into the environment of organisms modified or produced through genetic engineering that are plant pests or pose a plausible plant pest risk.

The petition for nonregulated status described in this notice was evaluated under the version of the regulations effective at the time that it was received. The Animal and Plant Health Inspection Service (APHIS) issued a final rule, published in the *Federal Register* on May 18, 2020 (85 FR 29790-29838, Docket No. APHIS-2018-0034)<sup>1</sup>, revising 7 CFR part 340; however, the final rule has been implemented in phases. The new Regulatory Status Review (RSR) process, which replaces the petition for determination of nonregulated status process, became effective on April 5, 2021, for corn, soybean, cotton, potato, tomato, and alfalfa. The RSR process is effective for all crops as of October 1, 2021. However, "[u]ntil RSR is available for a particular crop...APHIS will continue to receive petitions for determination of nonregulated

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<sup>1</sup>To view the final rule, go to [www.regulations.gov](http://www.regulations.gov) and enter APHIS-2018-0034 in the Search field.

status for the crop in accordance with the [legacy] regulations at 7 CFR 340.6.” (85 FR 29815). This petition for a determination of nonregulated status is being evaluated in accordance with the regulations at 7 CFR 340.6 (2020) as it was received by APHIS on January 28, 2020.

The petition (APHIS Petition Number 19-317-01p)<sup>2</sup> from BASF Corporation, of Research Triangle Park, NC (BASF), seeks a determination of nonregulated status of soybean (*Glycine max*) designated as event GMB151, which has been developed using genetic engineering for resistance to the plant-parasitic nematode, soybean cyst nematode (*Heterodera glycines*), and for tolerance to 4-hydroxyphenylpyruvate dioxygenase (HPPD-4) inhibitor herbicides. The BASF petition states that information collected during field trials and laboratory analyses indicates that GMB151 soybean is unlikely to pose a plant pest risk, and therefore should not be regulated under APHIS' regulations in 7 CFR part 340.

According to our process<sup>3</sup> for soliciting public comment when considering petitions for determinations of nonregulated status of organisms developed using genetic engineering, APHIS accepts written comments regarding a petition once APHIS deems it complete. In a notice published in the *Federal Register* on May 28, 2020 (85 FR 32004-32005, Docket No. APHIS-2020-0023),<sup>4</sup> APHIS announced the availability of the BASF petition for public comment. APHIS solicited comments on the petition for 60 days ending on July 27, 2020, in order to help identify potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition.

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<sup>2</sup> To view the petition, go to <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status>.

<sup>3</sup> On March 6, 2012, we published in the *Federal Register* (77 FR 13258-13260, Docket No. APHIS-2011-0129) a notice describing our process for soliciting public comments and information when considering petitions for determinations of nonregulated status for organisms developed using genetic engineering. To view the notice, go to <http://www.regulations.gov> and enter APHIS-2011-0129 in the Search field.

<sup>4</sup> To view the notice, petition, supporting documents, and the comments that we received, go to [www.regulations.gov](http://www.regulations.gov) and enter APHIS-2020-0023 in the Search field.

APHIS received nine comments on the petition from agricultural trade groups, farmers, and members of the public. Five comments generally supported BASF's petition, while four expressed objections to crops developed or modified through genetic engineering.

APHIS decided, based on its review of the petition and its evaluation and analysis of the comments received during the 60-day public comment period on the petition, that the petition involves an organism developed using genetic engineering that raises substantive new issues. According to our public review process for such petitions (see footnote 3), APHIS is following Approach 2, in which we first solicit written comments from the public on a draft environmental assessment (EA) and a draft plant pest risk assessment (PPRA) for a 30-day comment period through the publication of a *Federal Register* notice. Then, after reviewing and evaluating the comments on the draft EA and the draft PPRA and other information, APHIS revises the draft PPRA as necessary and prepares a final EA. APHIS also publishes a notice in the *Federal Register* announcing the regulatory status of the organism developed using genetic engineering and the availability of APHIS' final EA, PPRA, finding of no significant impact (FONSI), and our regulatory determination.

A second opportunity for public involvement was provided on August 17, 2021, with a notice published in the *Federal Register* (86 FR 45955-45956) announcing the availability of the draft EA and draft PPRA for public review and comment. That comment period closed on September 16, 2021. APHIS received 2,743 comments on the petition and supporting documents. All but eight of the comments consisted of identical and near-identical copies of a form letter submitted by different individuals who expressed their general opposition to the concept and use of genetic engineering for any purpose. Commenters objected to GMB151 soybean because it expresses a novel protein from *Bacillus thuringiensis*, which many stated has not been adequately evaluated for use as a pesticide. Others objected to deregulation of GMB151 soybean on grounds that it would contribute to weed resistance. Commenters also opposed deregulation because it

would contribute to an increase in the use of isoxaflutole, which they stated will jeopardize human health and safety. The comments are addressed in our final EA.

#### National Environmental Policy Act

The final EA contains the results of APHIS' review and evaluation of the comments received during the comment period on the draft EA, draft PPRA, and the petition. The final EA provides the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the determination of nonregulated status of GMB151 soybean. The EA was prepared in accordance with: (1) National Environmental Policy Act (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372). Based on our EA, the response to public comments, and other pertinent scientific data, APHIS has reached a FONSI with regard to the preferred alternative identified in the EA (to make a determination of nonregulated status of GMB151 soybean).

#### Determination

Based on APHIS' analysis of field and laboratory data submitted by BASF, references provided in the petition, peer-reviewed publications, information analyzed in the EA, the PPRA, comments provided by the public, and information provided in APHIS' response to those public comments, APHIS has determined that GMB151 soybean is unlikely to pose a plant pest risk and therefore is no longer subject to our regulations governing the importation, interstate movement, or release into the environment of organisms developed using genetic engineering.

Copies of the signed determination document, PPRA, final EA, and FONSI, as well as the previously published petition and supporting documents, are available as indicated in the ADDRESSES and FOR FURTHER INFORMATION CONTACT sections of this notice.

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 10th day of March 2022.

**Anthony Shea,**

*Administrator,*

*Animal and Plant Health Inspection Service.*

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